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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,123	10/20/2000	Michael C. Barney	661005.90268	7800

26710 7590 12/20/2004

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/693,123	BARNEY ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/06/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged if applicants' amendment, request for extension of time and request under 1.114, all filed 10/06/2004.

Claims 1-4 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/06/2004 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,548,552 ('552) in view of US 6,313,178 ('178).

US '552 teaches an absorbent article having additives in a sufficient amount that reduce the toxic shock syndrome toxin production (abstract). The additives are applied to the surface of the absorbent article then dried (col.3, lines 11-20). The absorbent article can be any absorbent article where reduction in toxic shock syndrome toxin production might be beneficial (col.9, lines 50-51).

US '552 does not teach the use of hexahydrolupulone or tetrahydroisohumulone in particular to treat toxic shock syndrome.

US '178 teaches a composition and method for inhibiting the *Staphylococcus aureus* growth. The method comprises contacting the bacteria with an effective amount of hexahydrolupulone (hexahydro-beta acid) or tetrahydroisohumulone (tetrahydroiso-alpha acid). The composition is formulated in an aqueous base water, alcohol,

propylene glycol or glycerin. The composition is suitable for topical administration to the epidermis (abstract; col.1, lines 30-35; col.2, lines 1-57; col.3, lines 57-62; col.4, lines 63-67; col.5, lines 42, 54-57; col.7, lines 25-29). The hexahydrolupulone and tetrahydroisohumulone are particularly effective against gram-positive bacteria such as *Staphylococcus aureus* (col.2, lines 10-15).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a dry absorbent article that has additives to treat toxic shock syndrome applied to its surface as disclosed by US '552, and replace the additives that treat toxic shock syndrome by hexahydrolupulone or tetrahydroisohumulone as disclosed by US '178, motivated by the teaching of US '178 that hexahydrolupulone or tetrahydroisohumulone are particularly effective against gram positive bacteria such as *Staphylococcus aureus*, with reasonable expectation of having a dry absorbent article with hexahydrolupulone or tetrahydroisohumulone on its surface to inhibit the growth of *Staphylococcus aureus* infection, and consequently, controlling toxic shock syndrome with success.

Response to Arguments

5. Applicant's arguments filed 10/06/2004 have been fully considered but they are not persuasive.

The main gist of applicant's argument against the rejection of claims 1-4 as being unpatentable under U.S.C. 103 (a) over US '552 in view of US '178 is that the references fail to teach the use of the tetrahydroiso-alpha acids or hexahydro-beta acids

at the recited concentration levels and the acidic environment of the amended claims. Applicants admit that US '178 teaches such compounds, but argue that the reference does not teach the claimed concentration particularly in the acidic environment of the liquid, i.e. urine, and applicants presented data on the activity of the compounds in acidic environments. The prior art does not teach increased sensitivity of *Staphylococcus aureus* in acidic environment. Applicants submit that all the features of the amended claims are not shown or suggested in US '552 and US '178.

In response to the above argument, the examiner position is that the only difference between the teaching of the prior art and the present invention is the claimed amount, and it is within the skill in the art with routine experimentation to optimize the amount of tetrahydroiso-alpha acids or hexahydro-beta acids disclosed by the prior art to inhibit the growth of *Staphylococcus aureus* because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233. Regarding the acidic liquid, i.e. urine, it is not part of the claimed invention method and article because the present method for inhibiting the *Staphylococcus aureus* and toxic shock syndrome requires applying diaper comprising tetrahydroiso-alpha acids or hexahydro-beta acids, and it is obvious that diaper is applied in contact with the acidic urine. Regarding the sensitivity of *Staphylococcus aureus* in acidic environment, it is well known in the art that acidity inhibits the deleterious effects of *Staphylococcus aureus* and elevated pH allows *Staphylococcus aureus* to produce toxic shock toxins, see US 5,592,949, col.2, lines 22-37. Therefore, the art recognized the effect of acidic

medium on the inhibition of the *Staphylococcus aureus* and the effect of higher pH on the production of toxic shock toxins. Therefore, the invention as whole is a prima facie obvious over the cited art.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

I. Ghali